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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,703	06/27/2000	Markus Pompejus	BGI-129CP	3829

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/605,703	Applicant(s) POMPEJUS ET AL.	
	Examiner Marjorie Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

R strictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 8-16, drawn to an isolated nucleic acid encoding an MCP protein, and a vector and host cell comprising the nucleic acid, classified in class 536, subclass 23.7. See also the election of species requirement set forth below.

II. Claims 3 and 6-8, drawn to an isolated nucleic acid from Appendix A, classified in class 536, subclass 23.7.

III. Claims 4-5 and 8, drawn to an isolated nucleic acid encoding a peptide from Appendix B, classified in class 536, subclass 23.7.

IV. Claim 17, drawn to a method of producing a polypeptide, classified in class 435, subclass 69.1.

V. Claims 18-19 and 22, drawn to an isolated MCP polypeptide, classified in class 530, subclass 350.

VI. Claims 20-21 and 24, drawn to an isolated polypeptide from Appendix B, classified in class 530, subclass 350.

VII. Claim 23, drawn to an isolated polypeptide encoded by a polynucleotide from Appendix A, classified in class 530, subclass 350.

VIII. Claims 25-34, drawn to a method of producing a fine chemical, classified in class 435, subclass 41. See also the election of species requirement set forth below.

IX. Claim 35, drawn to a method of detecting Corynebacterium diphtheriae, classified in class 435, subclass 6.

X. Claims 36-38, drawn to a host cell comprising a disrupted or modified nucleic acid from Appendix A, classified in class 536, subclass 23.7.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are separate and distinct from Groups V-VII because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups V-VII, the critical feature is a polypeptide whereas for Groups I-III the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group VII to be directed as to its synthesis by a polynucleotide of Group II, for example, however, the completely separate chemical types of the inventions of Groups I-III versus Groups V-VII supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I-III are not related. Although all of Groups I-III recited isolated nucleic acids, the nucleic acids of Group I are not limited to be the same of those in Groups II or III; nor are the nucleic acids of Group II limited to be the same as those of Group III. Each nucleic acid sequence is a separate and distinct structure; each structure is considered an independent invention. As each of Groups I-III recite different sequences/products, the Groups are not related.

Invention I is related to Inventions IV and VIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells comprising a vector of Group I may be used in either of the methods of Groups IV or VIII.

Invention I is not related to Invention IX. The method of Group IX does not recite use or detection of the nucleic acids of Group I and the nucleic acids of Group I are not limited to be those used in the method of Group IX, therefore the Groups are not related.

Invention I is not related to Invention X. The host cells of Group X are not limited to comprise the nucleic acids of Group I, and the nucleic acids of Group I are not limited to be those for inclusion in the host cells of Group X, therefore the Groups are not related.

Neither of Inventions II or III is related to either of Inventions IV or VIII. None of the methods of Groups IV or VIII recite use of the nucleic acids of either Group II or Group III. None of the nucleic acids of Groups II or III is limited to be one used in the methods of Groups IV or VIII. For these reasons, neither of Groups II or III is related to either of Groups IV or VIII.

Inventions II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group II may be used in methods to produce recombinant cells or in methods to produce proteins.

Inventions II and X are separate and distinct. The Groups are related in that the cells of Group X comprise nucleic acids related to those of Group II. However, the nucleic acids of Group X are limited to be disrupted or modified, and are therefore necessarily different sequences than those of Group II. As the host cells of Group X comprise different sequences

than those recited in Group II, and are not limited to comprise the sequences of Group II, Groups II and X are separate and distinct.

Group III is not related to either of Groups IX or X. The method of Group IX does not recite use of the nucleic acids of Group III, and the host cells of Group X are not limited to comprise the nucleic acids of Group III. In addition, the nucleic acids of Group III are not limited to be those for use in the method of Group IX nor to be those included in the host cells of Group X. For these reasons, Group III is not related to either of Groups IX or X.

Group IV is not related to any of Groups V-VII or IX-X. The method of Group IV is not limited to produce any of the polypeptides of Groups V-VII, and none of the polypeptides of Groups V-VII is limited to be one produced by the method of Group IV, therefore Group IV is not related to any of Groups V-VII. The methods of Groups IV and IX are directed to different results and recite different method steps and use of different products, therefore Groups IV and IX are not related. Group IV is not limited to use the host cells of Group X, nor are the host cells of Group X limited to be those for use in the method of Group IV, therefore Group IV is not related to Group X.

Groups IV and VIII are separate and distinct. The Groups are related in that each recites use of the same host cell of Group I; however, the methods are directed to different results. The method of Group IV is directed to produce a polypeptide, but is not limited to produce a fine chemical as recited in claim 31, for example. The method of Group VIII is not limited to produce a polypeptide. As the methods are directed to different results, the Groups are separate and distinct.

Groups V-VII are not related. Each of Groups V-VII recites a different polypeptide and therefore directed to a different product. As the Groups recite different products, they are not related.

None of Groups V-VII is related to either of Groups VIII or X. The method of Group VIII does not recite use or production of any of the polypeptides of Groups V-VII. The host cells of Group X are not limited to comprise or to be ones producing any of the polypeptides of Groups V-VII, and none of the polypeptides of Groups V-VII is limited to be one produced by the method or cells of Groups VIII or X. For these reasons, none of Groups V-VII is related to either of Groups VIII or X.

Neither of Groups V or VII is related to Group IX. The method of Group IX is not limited to use or produce the polypeptides of Group V or Group VII, and the polypeptides of Groups V and VII are not limited to be those for use in the method of Group IX, or to be produced by the method or Group IX. For these reasons, Group IX is not related to either of Groups V or VII.

Inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group IX may be used with the nucleic acids of Group II.

Groups VIII and IX are not related. The method recite different method steps, use of different products and are directed to different results. In addition, the method of Group IX does not recite use of the product of Group VIII. For these reasons, the Groups are not related.

Neither of Groups VIII or IX is related to Group X. The host cells of Group X are not limited to be those for use in either or the methods of Groups VIII or IX. Neither of the methods of Groups VIII or IX recite use or production of the host cells of Group X. For these reasons, Group X is not related to either of Groups VIII or IX.

Because these inventions are distinct for the reasons given above and the search required for Groups II-X is not required for Group I, the search for Groups I and III-X is not required for Group II, and the search for Groups I-II and IV-X is not required for Group III, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: fine chemicals as recited in claims 16 and 31.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed fine chemical for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15, 25-30 and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if

the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement applicable to all Groups, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention AND species AND the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

With regard to claims referring to appendices and/or tables, applicant is reminded that according to MPEP 2173.05(s):

> "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)."

Applicant is encouraged to consider amending the claims to recite SEQ ID NO's. The examiner further suggests that applicant review the appendices and specification to ensure that they are in compliance with 37 CFR 1.821 (d), which states that,

> "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

The examiner notes that appendices A (535 pages) and B (162 pages) were filed with the application on 6/27/00. Unfortunately, both appendices have become separated from the specification and are not available for review and examination by the examiner. The examiner apologizes for the inconvenience and requests that applicants supply a supplementary copy of Appendices A and B with the response to this restriction/election requirement.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 872-9306 (Right FAX). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

January 24, 2002